

Drug Update 2023: Newest medication approvals

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Owner – Partners in Healthcare Education, LLC
Faculty – Fitzgerald Health Education Associates
Lawrence, MA

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Disclosure

- Speaker Bureau
 - Sanofi-Pasteur, Merck, Pfizer, Seqirus, Moderna – Vaccines
 - AbbVie and Biohaven – Migraines
 - Idorsia – Insomnia
 - Exact Sciences – Colorectal Cancer Screening
 - AstraZeneca – Asthma
- Consultant
 - Sanofi-Pasteur, Merck, Pfizer, Moderna, and Seqirus – Vaccines
 - GlaxoSmithKline – OA and Pain
 - Bayer – Chronic Kidney Disease
 - Idorsia – Insomnia
 - Shield Therapeutics – Iron Deficiency Anemia
- All relevant financial relationships have been mitigated.

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Objectives

- At the end of this presentation, the participant will be able to:

1. Identify several new medications.
2. Discuss the use, adverse effects, drug-drug interactions, and benefits of each of the medications.
3. Discuss updates related to labeling, indications, and risks associated with various medications.

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Tips



- References
 - Listed throughout and at the end of the presentation
- To facilitate your learning
 - Specific tables/images can be viewed full page at the end of your handout.

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New Drugs

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<p>Center for Drug Evaluation and Research (CDER) 2022 Data¹</p>	<ul style="list-style-type: none"> • 37 new medications approved • Majority: Oncology, biologics (asthma, psoriasis), rare/orphan diseases
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<p>Center for Drug Evaluation and Research (CDER) 2023 Data²</p>	<p>Since January 2023, 14 novel medications have been approved.</p>
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<p>■ Women's Health</p>

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Ibrexafungerp (Brexafemme®)³

Ibrexafungerp

- Class
 - Antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis
 - **New indication: Reduction of recurrent infections**
 - Inhibits glucan synthase, an enzyme involved in the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall

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Ibrexafungerp (Brexafemme®)³ (continued)

Ibrexafungerp (cont.)

- Class (cont.)
 - Has activity against the following species: *Candida auris*, *Candida dubliniensis*, *Candida glabrata*, *Candida guilliermondii*, *Candida kefyr*, *Candida krusei*, *Candida lusitanae*, *Candida parapsilosis*, *Candida tropicalis*
 - *In vitro* activity against –azole resistant strains

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Ibrexafungerp (Brexafemme®)³ (continued)

- Dosage
 - Acute treatment: 300 mg twice daily × 1 day (600 mg total)
 - **Available in 150 mg tablets**
 - Administer 12 hours apart.
 - With or without food
 - Recurrence reduction
 - 300 mg PO every 12 hours × 1-day
 - Administer on the same day every month.

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EKO

Contraindications

- 13

- 14

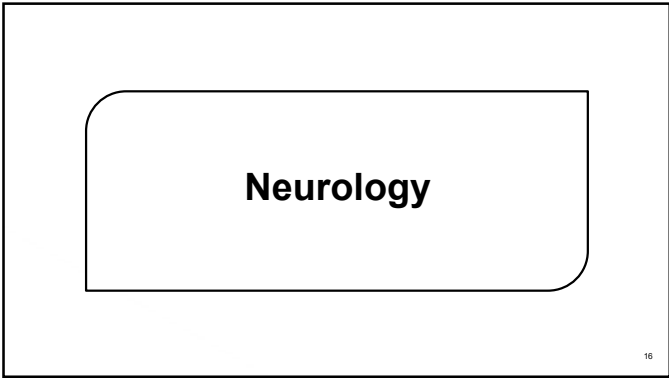
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- 1

Slide 13

RKO Wendy, please see first box. "Is childbearing" or "of childbearing"
Thanks
Renee Kirshner, 2023-07-24T18:20:55.845

LD0 0 I changed it to 'of'
Larlene Dunsmuir, 2023-07-25T16:40:11.466



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Lecanemab-irmb (Leqembi®)⁴

- Class
 - An amyloid beta-directed antibody which in clinical trials demonstrated a reduction in amyloid beta plaques
 - Recombinant human immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta
- Indication
 - Initiated in the mild cognitive impairment or mild stage of dementia from Alzheimer's disease

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Reduction in Amyloid Beta PET Composite

Figure 1: Reduction in Brain Amyloid Beta Plaque (Adjusted Mean Change from Baseline in Amyloid Beta PET Composite, SUVR and Centiloids) in Study 1

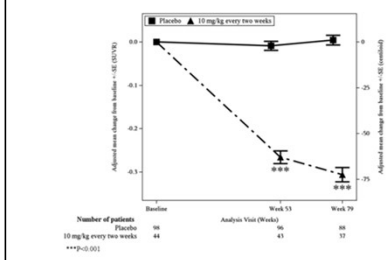


Image source: FDA. (2023). Lecanemab-irmb (Leqembi®). https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761269Orig1s0000bl.pdf

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ADAS-Cog14⁵

- Baseline to 18 months
 - Baseline: 24.45 (drug arm) vs. 24.37 (placebo)
 - Mean change from placebo at 18 months
 - 4.14 (drug) vs. 5.581 (placebo)
 - Statistical significance: p=0.00065

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Lecanemab-irmb (Leqembi®)⁵ (continued)

- Dosage: 10 mg/kg administered via IV solution over 1-hour every 2 weeks
- Testing before and during treatment
 - MRI prior to initiation and...
 - MRI prior to 5th, 7th, and 14th infusions

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Lecanemab-irmb (Leqembi®)⁵ (continued)

Adverse related events

- Amyloid related imaging abnormalities (ARIA) including ARIA-E (edema) and ARIA-H (hemosiderin deposition)
- Depending upon severity and symptoms, dosing may be continued, suspended or discontinued.

- Symptomatic ARIA occurred in 3% (29/898) of patients treated with Lecanemab in study 2 with serious symptoms reported in 0.7% (6/898).
- Clinical symptoms associated with ARIA resolved in 79% (23/29) of patients during the period of observation.
- Similar findings were observed in Study 1.

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Learning More About This Class⁵

- We are starting to learn...
 - ApoE ε4 homozygotes patients
 - Those treated with this class of medications have a higher incidence of ARIA, including symptomatic and serious ARIA, compared to heterozygotes and noncarriers.
 - Testing for ApoE ε4 status should be performed prior to initiation of treatment to inform the risk of developing ARIA.
 - Prior to testing, prescribers should discuss with patients the risk of ARIA across genotypes and the implications of genetic testing results.

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Now What...

- Lecanemab is the first product in this class to be fully FDA approved and thus, covered.
- The Centers for Medicare and Medicaid Services (CMS) has announced that it will provide Medicare coverage for new Alzheimer's drugs if they receive traditional approval from the Food and Drug Administration (FDA).

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Zavegepant (Zavzpret™)⁶

- **Name:** Zavegepant
- **Class:** gepant (CGRP antagonist)
- **Indication**
 - Adults with acute migraine with and without aura
- **Dose**
 - 10 mg via a single spray into one nostril at the onset of migraine (Maximum dose in 24-hour period is 10 mg.)

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Zavegepant (Zavzpret™)⁶ (continued)

- **Efficacy**
 - Two, double-blind, placebo-controlled trials
 - **Study 1**
 - N=623 (drug) and N=624 (placebo)
 - Pain free at two hours: 23.6% vs. 14.9% (p<0.001)
 - Most bothersome symptom free at 2 hours: 39.6% vs. 31.1% (p 0.001)
 - **Similar findings in Study 2**
 - Also looked at return to normal function, pain relief, sustained pain freedom at 48 hours

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Zavegepant (Zavzpret™)⁶ (continued)

- Adverse events (drug vs. placebo)
 - Taste disorders (18% vs. 4%)
 - Nausea (4% vs. 1%)
 - Nasal discomfort (3% vs. 1%)
 - Vomiting (2% vs. <1%)

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Zavegepant (Zavzpret™)⁶ (continued)

Drug Interactions

- Zavegepant is a 3A4 substrate but no significant interactions with 3A4 inhibitors or were inducers seen.
- OATP1B3 inducers
 - Has not been studied however, may decrease AUC of Zavegepant

- OATP1B3 inhibitors
 - Coadministration with rifampin
 - Strong OATP1B3 inhibitor **and**
 - 3A inducer resulted in an increase in AUC of Zavegepant 2.3-fold.

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Zavegepant (Zavzpret™)⁶ (continued)

Drug Interactions (cont.)

- OATP1B3 inducers
 - Has not been studied however, may decrease AUC of Zavegepant

- Intranasal decongestants
 - May decrease the efficacy of Zavegepant
 - If absolutely needed, use 1-hour or more after Zavegepant.

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Zavegepant (Zavzpret™)⁶ (continued)

- Precautions/contraindications
 - Avoid use in pregnancy and lactation.
 - Animal models did not demonstrate any issues, but inadequate safety data.
 - No indication in children
 - Avoid use in patients with severe hepatic impairment (no studies).
 - Avoid use in patients with creatinine clearance of <30 mL/min.
- Cost
 - \$1,168.00 for 6 sprays (devices) per drugs.com

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Respiratory



Image source: Microsoft stock image

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Albuterol and Budesonide Inhaler⁷

- Name: **Albuterol and budesonide (Airsupra™)**
- Class: SABA/ICS
- Indication: As needed treatment for acute bronchospasm or prevention of bronchospasm and to reduce the risk of acute asthma exacerbations in adults 18 years of age and older
- Dosage: 180 mcg of albuterol and 160 mcg of budesonide
 - Dosed: 2 puffs every 4 hours as needed
 - Do not exceed 6 doses (12 puffs) in 24 hours.

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Albuterol and Budesonide Inhaler⁷ (continued)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Adverse effects<ul style="list-style-type: none">▪ Oral candidiasis: Should instruct to rinse mouth out.▪ Caution: DPI – Acute paradoxical bronchospasm | <ul style="list-style-type: none">• Why a combination?<ul style="list-style-type: none">▪ GINA and EPR4 recommend use of ICS whenever SABA is needed to prevent/reduce exacerbations and the need for systemic corticosteroids.▪ Provides ICS/SABA in one inhaler thus decreasing copays |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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34

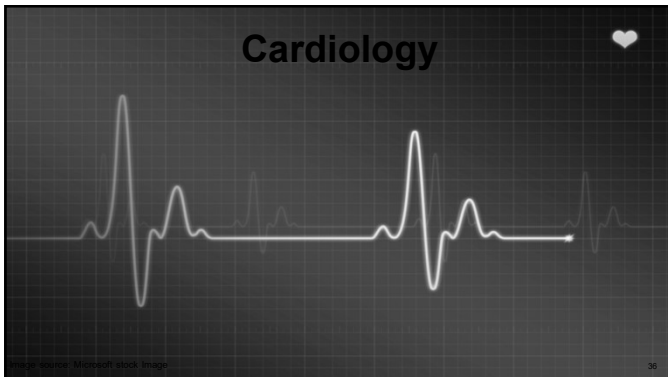
Albuterol and Budesonide Inhaler⁷ (continued)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Drug interactions<ul style="list-style-type: none">▪ Budesonide<ul style="list-style-type: none">• CYP450 3A4 substrate• Avoid strong 3A4 inhibitors as they may increase systemic exposure of budesonide.• Not currently approved for children | <ul style="list-style-type: none">• Will not be available until early 2024• Canister will have a dosing counter on it to enable patient to see how many doses remain.• Cost: Has not been announced |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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Cardiology



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Newest Agent

- **Inclisiran (Leqvio®)**
 - Indication: Add on to maximally tolerated statin to lower LDL-C for adults with...
 - Heterozygous familial hypercholesterolemia
 - Atherosclerotic cardiovascular disease
 - Primary hyperlipidemia

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Inclisiran (continued)

- Mechanism of action⁸
 - A small interfering RNA (siRNA) directed to PCSK9 mRNA
 - Works by increasing LDL-C receptor recycling and expression on the hepatocyte cell surface, which increases LDL-C uptake and lowers LDL-C levels in the circulation

- Dosage: 284 mg subcutaneous injection
 - Administered day 0, then day 3 months, then every 6 months
 - Administered by healthcare provider

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Inclisiran⁸ (continued)

- Efficacy (Study 1): Patients with hyperlipidemia and ASCVD already on maximally tolerated statin
 - Change from baseline was evaluated
 - LDL: 51% reduction
 - Total cholesterol: 34% reduction
 - Non-HDL-C: 47% reduction
 - ApoB: 45% reduction

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Slide 38

LDO Wendy, on first pink bullet, left hand side- would it make sense to add 'chemically synthesized small" so that it reads "A chemically synthesized small interfering RNA..."?

Larlene Dunsmuir, 2023-07-26T17:21:02.208

Inclisiran⁸ (continued)

• Studies

▪ 1,833 patients treated with inclisiran in clinical studies

▪ 981 (54%) patients were 65 years of age and older

▪ 239 (13%) patients were 75 years of age and older

▪ No overall differences in safety or effectiveness were observed between patients 65 years of age and older and younger adult patients.

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Inclisiran⁸ (continued)

• Adverse events (drug vs. placebo)

▪ Injection site reaction (8% vs. 2%)

▪ Arthralgia (5% vs. 4%)

▪ Bronchitis (4% vs. 3%)

• Precautions/contraindications

▪ Avoid in pregnant women (may cause fetal harm)

▪ Avoid in lactation (no safety information available)

▪ Avoid in pediatric patients

▪ Has not been studied in severe liver or kidney disease

• Cost: \$3,250.00 per dose

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Endocrinology

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Bexagliflozin (Brenzavvy™)⁹

- Class: SGLT2-I
- Indication: Adults with type 2 diabetes
 - No additional indication beyond diabetes currently
 - In pivotal trials: 10.1% receiving placebo experience Major Adverse Cardiovascular Events (MACE) vs. 7.9% receiving bexagliflozin

LDL

- Dosage: 20 mg once daily taken in the morning
 - Check GFR prior to starting medication.
 - Do not initiate in individuals with GFR <30 mL/min.

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[illegible]

Bexagliflozin (Brenzavvy™)⁹ (continued)

- Efficacy (23 clinical trials performed)
 - Decrease in A1C from baseline (0.5% vs. placebo of 0.1%)
 - 31% of patients achieved A1C of <7% (0.07 proportion).
 - Trial 2: A1C decrease 1.0% vs. placebo of 0.5%
 - 26% achieved A1C of <7.0% (0.07 proportion)

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Bexagliflozin (Brenzavvy™)⁹ (continued)

- Adverse events (drug vs. placebo)
 - Increased urination: 7% vs. 3%
 - UTI: 6% vs. 4%
 - Female genital mycotic infections: 6% vs. 0%
 - Thirst: 3% vs. 2%

Slide 43

LD0 Wendy, do you want to spell out Major Adverse Cardiac Effects (MACE)?

Larlene Dunsmuir, 2023-07-26T19:09:54.777

WW0 0 done

Wendy Wright, 2023-07-26T21:03:14.857

Bexagliflozin (Brenzavvy™)⁹ (continued)

- Precautions/warnings
 - Carries same warnings and precautions as all other SGLT2Is
 - Euglycemic DKA, genital mycotic infections, UTI/urosepsis, Fournier's gangrene, lower extremity amputations
 - Avoid use in pregnancy/lactation
 - Discontinue 3 days before any surgery.

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Bexagliflozin (Brenzavvy™)⁹ (continued)

- Drug-drug interactions
 - No evidence of significant drug-drug interactions
- Cost: \$47.85 for 30 days ***This will be the marketing tool.
- FYI: This will be the first SGLT2I approved for cats with diabetes.

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Tirzepatide (Mounjaro™)¹⁰

- Class: GIP/GLP-1 agonist
 - Works by increasing insulin secretion, decreasing glucagon secretion, increasing insulin sensitivity and delaying gastric emptying
- Indications
 - Type 2 diabetes (adults only)
 - It is not indicated for type 1 diabetes.

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Tirzepatide¹⁰ (continued)

- Class: GIP/GLP-1 agonist (cont.)
 - Dosing
 - 2.5 mg SC once weekly × 4 weeks; then 5 mg once weekly × 4 weeks; then 7.5 mg once weekly × 4 weeks; then 10 mg once weekly × 4 weeks; then 12.5 mg once weekly × 4 weeks
 - Maximum: 15 mg once weekly

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Tirzepatide¹⁰ (continued)

- Clinical trials/efficacy
 - 1539 (30.1%) were 65 years of age or older, and 212 (4.1%) were 75 years of age or older

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Tirzepatide¹⁰ (continued)

- Clinical trials/efficacy (cont.)
 - 5 clinical trials to assess efficacy: SURPASS 1–5
 - 40-week monotherapy trial
 - A1C baseline: 8.1%, 8.0%, 7.9%, 7.9% (0.081, 0.08, 0.079, 0.079 proportion)
 - A1C 40 weeks (placebo, 5 mg, 10 mg, and 15 mg)
 - -0.1%, -1.8%, -1.7%, -1.7%
 - Weight baseline
 - -1.0 kg, -6.3 kg, -7.0 kg, -7.8 kg

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Tirzepatide¹⁰ (continued)

- Precautions/warnings
 - No hepatic and renal dosing adjustments
 - Caution: History of gastroparesis or pancreatitis
 - Caution when adding to medications with narrow therapeutic index
 - Do not use in pregnancy; no data on impact in lactation

- Contraindications
 - Patients with medullary thyroid carcinoma or family history of such
 - Patients with multiple endocrine neoplasia syndrome

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Tirzepatide¹⁰ (continued)

- Adverse reactions (placebo, 5 mg, 10 mg, and 15 mg)
 - Nausea: (4%, 12%, 15%, 18%)
 - Diarrhea: (9%, 12%, 13%, 17%)
 - Decreased appetite: (1%, 5%, 10%, 11%)
 - Vomiting: (2%, 5%, 5%, 9%)
 - Constipation: (1%, 6%, 6%, 7%)
- Cost: Approximately \$1,000 for 4 weeks
 - Numerous copay cards are available online.

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Teplizumab-mzwv (Tzield™)¹¹

- Class: Anti-CD3 antibodies
- Indication
 - Diabetes mellitus type 1, stage 2
 - 8 years of age and older
 - Exact MOA is unknown.
 - Binds to CD3, may produce deactivation of pancreatic beta cell autoreactive T cells

- Dosing
 - IV titration schedule from "day 1 to day 14" (30 minute minimum)
 - Premedicate with antipyretic, antihistamine, **and/or** antiemetic prior to 1st 5 doses, then as needed.

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Teplizumab-mzwv¹¹ (continued)

- Prior to initiation, must confirm type 1 diabetes stage 2.
 - Confirm stage 2 T1DM by documenting **at least two** positive pancreatic islet autoantibodies in those who have dysglycemia without overt hyperglycemia using an oral glucose tolerance test (OGTT) or alternative method if appropriate and OGTT is not available.
 - CBC and hepatic panel are required.
 - Make sure all vaccinations are up to date (at least 8 weeks before treatment initiation).

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Teplizumab-mzwv¹¹ (continued)

- Monitoring
 - Discontinue if AST or ALT is 5× or more upper limits of normal.
 - CBC: Monitor white count and discontinue if severe lymphopenia occurs.
 - Monitor for serious infections. May need to discontinue or place on hold if it occurs
 - Acute hypersensitivity reactions

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Teplizumab-mzwv¹¹ (continued)

- Clinical trial efficacy
 - In Study TN-10, stage 3 type 1 diabetes was diagnosed in 20 (45%) of the teplizumab patients and in 23 (72%) of the placebo-treated patients.
 - Median time from randomization to stage 3 type 1 diabetes diagnosis was 50 months in the teplizumab group and 25 months in the placebo group.

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Quick Updates and Additional Approvals

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Norgestrel (Opill®)

- FDA voted in favor: RX – OTC switch
 - Progestin only, once daily oral contraceptive
 - Indication: Prevention of pregnancy
 - Awaiting final approval summer 2023 making pill available by end of 2023
- **July 14, 2023: Approved by FDA. No released date of availability or cost.**

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Naloxone Nasal Spray (Narcan®)¹²

- Approved for OTC switch
- Available by end of summer 2023 in all states
- 4 mg nasal spray
- Safe to administer to adults, adolescents, and children

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New Indication: Linaclotide

- **Linaclotide (Linzess®)**
- Indication: Approved for children ages 6 years and older with functional constipation
- 72 mg once daily dose
- Contraindicated in children ages 2 years and younger

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Boxed Warning¹³

- All ADHD drugs
 - FDA statement: "Patients should never share their prescription stimulants with anyone, and the boxed warning will describe the risks of misuse, abuse, addiction, and overdose consistently for all medicines in the class."

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New Indication

- **Brexpiprazole (Rexulti®)**¹⁴
 - Agitation associated with Alzheimer's disease
 - Dosing
 - 0.5 mg on day 1–7
 - 1 mg on day 8–14
 - Recommended target dose: 2 mg
 - Maximum dose: 3 mg
 - Adverse effects: Headache, dizziness, sleep disturbances
 - Boxed warning remains in effect

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New Indications

<ul style="list-style-type: none">• Semaglutide (Wegovy®)¹⁵<ul style="list-style-type: none">▪ Approved 2.4 mg once weekly dosage for use in adolescents 12 years of age and older with obesity▪ Defined as<ul style="list-style-type: none">• BMI at or above the 95th percentile for age and sex	<ul style="list-style-type: none">• Phentermine/topiramate (Qsymia®)<ul style="list-style-type: none">▪ Approved for 12 years of age and older with obesity
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New

- **Secnidazole¹⁶ (Solosec[®])**
 - Approved for the treatment of trichomoniasis
 - 2 grams as a single dose
 - **Also, new approval**
 - 12 years of age and older for Bacterial Vaginosis (BV) and trichomoniasis
- Azelastine hydrochloride nasal spray, 0.15% approved for OTC sales; individuals ages 6 years and older

Approval

- **Fluticasone/umeclidinium/vilanterol (Trelegy™ Ellipta)**
 - Approved for asthma maintenance
- **Capsaicin 8% patch (Qutenza®)**
 - Approved for DPN of the feet
- **Levonorgestrel-releasing intrauterine system (Mirena®)**
 - Approved for use up to 8 years

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Slide 65

RK0 Does BV need to be written out or is it a common abbreviation? Is it bacterial vaginosis?

Renee Kirshner, 2023-07-24T15:41:19.831

LDO 0 It is bacterial vaginosis. OK to leave as BV.

Larlene Dunsmuir, 2023-07-26T20:34:16.530

Slide 66

RK0 Does DPN need to be written out or is it widely understood? If so, just dbl checking it's Diabetic peripheral neuropathy. Thanks

Renee Kirshner, 2023-07-24T18:52:53.318

LDO 0 I think it is widely understood but will let Wendy weigh in.

Larlene Dunsmuir, 2023-07-26T20:34:48.543

Latest Updates¹⁷

- FDA has removed EUA for tixagevimab/cilgavimab (Evusheld™)
 - Previously used for individuals who were immunocompromised to prevent COVID-19

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Latest Updates¹⁸ (continued)

- 2/2/2023: **Daprodustat (Jesduvroq®)** was approved for anemia of chronic kidney disease in patients on dialysis.
 - Hypoxia-inducible factor prolyl hydroxylase inhibitor (often referred to as HIF-PHI); increases intrinsic erythropoietin (EPO)
 - Oral agent
 - Competes with EPO products
 - Boxed warning: Thrombotic events

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Updated Indication

- **Atogepant (Qulipta™)**
 - New indication: Chronic migraine (15 or more migraine days per month)
 - Dose: 60 mg once daily
 - Class: CGRP antagonist
 - Efficacy begins within 1-week of starting medication.

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New Indication

- **Remdesivir (Veklury®)**¹⁹
 - FDA approved for the acute treatment of COVID-19 in children and adults
 - Now approved for treatment of individuals with severe renal impairment including those on dialysis

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Immunizations

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Respiratory Syncytial Virus Vaccine, Adjuvanted

- Name: **RSV virus vaccine (Arexvy)**²⁰
- Class: Vaccine
- Indication: Prevention of RSV in individuals 60 years of age and older
- Efficacy: 24,966 participants
 - 82.6% efficacy against RSV-LRTD in adults 60 years and older
 - 94.6% efficacy against RSV-LRTD in adults 60 years and older with at least one comorbidity (i.e., CV or DM)
 - 94.1% efficacy against severe RSV-LRTD

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Slide 72

RKO Larlene/Sally: FYI, I cannot find if Arexvy is registered and/or trademarked. I am going to leave as is unless you can find. It maybe too new.

Renee Kirshner, 2023-07-24T16:16:33.722

LD0 0 Trademark application has been filed but not authorized yet.

Larlene Dunsmuir, 2023-07-26T20:37:44.521

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Respiratory Syncytial Virus Vaccine, Adjuvanted²⁰
(continued)

- Dose: 0.5 mL single dose; delivered IM; must be reconstituted
- C/I: Any allergies to active ingredient
- Caution: Syncope
- Adverse events
 - Injection site pain (60.9%)
 - Fatigue (33.6%)
 - Myalgia (28.9%)
 - Headache (27.2%)
 - Arthralgia (18.1%)

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Respiratory Syncytial Virus Vaccine, Adjuvanted²⁰
(continued)

- Additional information: CDC – Fully approved
 - Medicare Part D payment
 - One and done for now (2 years)...studies ongoing
- Additional studies underway
 - Influenza coadministration
 - 50–59 years of age
 - Continued monitoring for Guillain-Barre and atrial fibrillation per FDA

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Respiratory Syncytial Virus Vaccine

- Name: **RSV virus vaccine (Abrysvo™)**²¹
- Class: Vaccine – Single dose
- Indication: Prevention of RSV in individuals 60 years of age and older
- Efficacy: Study 1: n=17,197 (vaccine) vs. n=17,186 (placebo)
 - First episode of RSV associated LRTD with 2 or more symptoms: 66.7%
 - First episode with 3 or more symptoms: 85.7%

75

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Slide 73

RKO What is C/I and should it be written out?
Renee Kirshner, 2023-07-24T18:54:48.016

LDO 0 Contraindications
Larlene Dunsmuir, 2023-07-26T20:38:22.701

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Respiratory Syncytial Virus Vaccine²¹ (continued)

- Dose: 0.5 mL single dose; delivered IM; must be reconstituted
- C/I: Any allergies to active ingredient
- Caution: Syncope
- Adverse events
 - Injection site pain (10.5%)
 - Fatigue (15.5%)
 - Myalgia (10.1%)
 - Headache (12.8%)
 - Arthralgia (7.5%)

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Respiratory Syncytial Virus Vaccine²¹ (continued)

- Additional information: FDA-approved
- Additional studies underway
 - ? Need for annual revaccination
 - Continued monitoring for Guillain-Barre
- Information
 - Medicare Part D payment
 - One and done for now

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RZV

- **Recombinant Zoster Vaccine (Shingrix®)**
- Approved by FDA for 18 years of age and older; immunocompromised
- Two dose series: Day 0 and day 1–2 months
- CDC: Now ages 19 years and up; immunocompromised

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Slide 76

RKO Please see comment on slide 73 regarding C/I. Whatever decision there, I will include/not include here. Thanks

Renee Kirshner, 2023-07-24T18:56:21.527

New

- Universal hepatitis B vaccination for all unvaccinated adults aged 19–59 years
 - Those with risk factors and aged 60 years and older should also be immunized against Hepatitis B.
- PCV 15 may now be substituted in children for PCV 13.
- MCV4 (Menactra®) is being replaced by MenQuadFi®.

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PCV 20

- FDA has approved PCV 20 for children.
 - To be used in infants and children

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Thank you!

I would be happy to entertain any questions or comments

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End of Presentation!

Thank you for your time, attention.

Wendy L. Wright,
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